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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/722,096	11/22/2000	Ernest G. Hope	12531-002001	4236

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BOSTON, MA 02110

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/722,096

Applicant(s)

HOPE, ERNEST G.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8,14-22,24,25 and 60-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,3,4,6-8,14-22,24,25 and 60-63 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 6/24/2003 (paper no. 13) is acknowledged and entered into the record. Accordingly, claims 2,5,9-13,23, and 26-59 are canceled. Claims 60-63 are newly added. It is noted that applicant has stated on page 4 of the response that claims 26-59 are canceled, while on page 5, paragraph two only claims 26-33 and 59 are noted as being canceled. Applicant is requested to clarify cancellation of claims in response to this office action.
2. Therefore, claims 1, 3-4,6-8,14, 22, 24-25, and 60-63 are pending and examined on the record.

New Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

3. Claims 1,3-4,6-8,14-22, 24-25, and 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. Applicant's amendment to claim 1 with the limitation of comparing CIK selectivity to unstimulated PBMCs is not supported in the specification or in the claims as originally filed. Applicant is required to remove such limitations from

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the claims or specifically indicate the support in the specification for the newly added limitation.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims are dependent on claims that have been canceled, as such the metes and bounds of the claims cannot be adequately determined.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 1, 14-21 and now newly added claims 60-63 under 35 USC 102(b) as being anticipated by Lu *et al* is maintained for the reasons of record. Applicant argues that examiner has not made a *prima facie* case of anticipation because the alleged inherent properties disclosed by Lu *et al* are seen as probabilities or possibilities. Applicant's arguments have been carefully considered but are not found persuasive. Lu *et al* disclose of a composition comprising CIK cells and further disclose the administration of said composition to a SCID mouse animal model. Lu *et al* further teach that the CIK cells generated and administered are capable of generating an anti-tumor response. The specification of the instant application discloses that CIK cells are generated by a method of adding cytokines to peripheral blood lymphocytes (PBL) in a specific manner (see example 1), of which is identical to the method of preparing CIKs

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taught by Lu *et al.* Furthermore, the specification also teaches that CIKs can be divided into three general categories, those that specifically recognize tumor cells, those that specifically recognize endothelial cells, and those that recognize both endothelial cells and tumor cells. Because the method of generating the CIKs taught by Lu *et al.* is identical to that taught in the instant specification, and because the patent office does not have the facilities to determine whether the CIKs taught by Lu *et al.* are indeed different clones or have different specificities for targets as claimed by the applicant, in the absence of evidence to the contrary, the CIKs taught by Lu *et al.* would also have damaging affects on tumor associated vasculature. Furthermore, because PBLs or PBMCs are unstimulated cells that have no cytotoxic effects or are anergic cells (see page 2), in general, the CIKs taught by Lu *et al.* would also have more activity when compared to unstimulated cells. Thus the percentage of activity claimed is an inherent property of all stimulated cells whether they have preference to tumor cells, endothelial cells or to both. As such the claims are currently interpreted are still anticipated by Lu *et al.*

All other rejections are withdrawn in view of the arguments presented thereto in paper no. 13.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
August 28, 2003